



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Benjamin Hurley; tel. 240-669-5092; benjamin.hurley@nih.gov. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Producing Modified Vaccinia Ankara (MVA) Virus with Continuous Mammalian

Cell Lines: Viral Host-range Factors for Increasing MVA Vaccine Production Yield

Description of Technology:

Modified vaccinia Ankara (MVA) based vaccines are being deployed in numerous human clinical trials for indications such as measles, malaria, HIV-1 and MERS to name a few. As with many vaccines, scale-up and production are significant challenges with the MVA platform. Not only are current large-scale MVA vaccine production processes inefficient (such as the cumbersome use of chick embryo fibroblast (CEF) cells), but a major bottleneck lies in limited host cell propagation options and a lack of viable continuous cell lines suitable for MVA vaccine production.

To address this need, scientists at NIAID have identified a number of key viral factors in MVA replication in mammalian cells and developed methods of modifying MVA viruses in a way that allows for the growth of MVA in cells that were previously considered unsuitable for such purpose. For example, NIAID scientists observed that the introduction of a serine protease inhibitor 1 (SPI-1) gene into the MVA genome led to more than a 2-log enhancement of virus spread in human diploid MRC-5 cells, whereas deletion of the gene diminished the spread of host-range extended viruses by similar extents. Additionally, MRC-5 cells stably expressing SPI-1 also enhanced replication of MVA.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Vaccine Development: recombinant MVA-based vaccine production in non-CEF cell lines.
- Therapeutic oncolytic virus: Recombinant MVA constructs encoding oncolytic tumor-suppressor proteins, pro-apoptotic proteins, cytokines, immunomodulatory

proteins, cytotoxic peptides, suicide proteins, cytotoxins, pro-drugs, therapeutic RNAs, etc.

Competitive Advantages:

- Recombinant MVA constructs for use in non-avian, continual cell line-mediated vaccine production.
- Efficient scale-up vaccine production as a result of higher viral yield, enhancing epidemic/pandemic preparedness.

Inventors: Bernard Moss, Linda Wyatt, Ruikang Liu, Jorge Mendez-Rios, all of NIAID

Publications:

Liu R, Mendez-Rios JD, Peng C, et al. SPI-1 is a missing host-range factor required for replication of the attenuated modified vaccinia Ankara (MVA) vaccine vector in human cells.; *PLoS Pathog.* 2019.

Peng C, Moss B. Repair of a previously uncharacterized second host-range gene contributes to full replication of modified vaccinia virus Ankara (MVA) in human cells. *Proc Natl Acad Sci U S A.* 2020.

Intellectual Property: HHS Reference No. E-076-2019; International Application No. PCT/US20/33788

Licensing Contact: To license this technology, please contact Benjamin Hurley at 240-669-5092 or benjamin.hurley@nih.gov, and reference E-076-2019.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this invention. For collaboration opportunities, please contact Benjamin Hurley; (240) 669-5092, benjamin.hurley@nih.gov.

Dated: June 2, 2021.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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